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HODGSON RUSS LLP
ONE M & T PLAZA
SUITE 2000
BUFFALO, NY 14203-2391

EXAMINER	
FETTEROLF, BRANDON J	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 05/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/779,949	PAULI ET AL.	
	Examiner	Art Unit	
	Brandon J. Fetterolf, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *5-6 and 9-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3 and 7* is/are rejected.

7)☒ Claim(s) *2,4 and 8* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 February 2004 and 23 August 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

The Election filed on March 24, 2006 in response to the Restriction Requirement of February 21, 2006 has been entered. Applicant's election of Group I, claims 1-4 and 7-8, has been acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The restriction requirement is therefore deemed to be proper and is made FINAL.

Claims 1-15 are currently pending.
Claims 5-6 and 9-15 are withdrawn from consideration as being drawn to non elected inventions.
Claims 1-4 and 7-8 are currently under consideration.

Species Election

The species election of SEQ ID NO: 50 is acknowledged. However, the requirement for the election of a species has been withdrawn in view of the peptides being free of the prior art.

Priority

Applicant's claim for domestic priority under 35 U.S.C. 120 is acknowledged. After reviewing the parent Applications, 10/055,412, now US Patent 6,692,939, 09/193,562, now US 6,309,857 and provisional application 60/065,922, for the disclosure of a peptide of about 10 amino acids comprising SEQ ID NO: 61, the Examiner has established a priority date of **February 17, 2004** consistent with the filing date of the instant application serial number 10/779,949. If applicant disagrees with any rejection of claim 7 set forth in this office action based on examiner's establishment of a priority date of **February 17, 2004** for the instant claims in application serial number 10/779,949 applicant is invited to submit evidence pointing to the serial number, page and line where support can be found establishing an earlier priority date.

Information Disclosure Statement

The Information Disclosure Statement filed on 6/30/2004 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. A signed copy of the IDS is attached hereto.

Specification

The disclosure is objected to because of the following informalities:

The specification on page 1 should be amended to reflect the priority status of the present application, for example: This application is a Continuation In Part of U.S. patent application Ser. No. 10/055,412 filed Oct. 29, 2001, now U.S. Pat. No. 6,692,939, which is a Divisional of U.S. patent application Ser. No. 09/193,562 filed on Nov. 17, 1998, now U.S. Pat. No. 6,309,857, which claims the priority of U.S. Provisional Application Ser. No. 60/065,922 filed on Nov. 17, 1997, the disclosures of which are incorporated herein by reference.

The specification on page 6, line 8 describes Fig. 13 as an illustration of electrophysiological analysis of hCLCA2. However, the description of Figure 13 taught in the specification does not appear to include the description of Figure 13A and 13B.

The specification on page 7 does not appear to describe the results set forth in Fig. 17C.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 3 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, the claims are inclusive of a genus of polypeptides which are a fragment of SEQ ID NO: 32 having a molecular weight of about 90kDa or 35 kDa and comprising the amino acid sequence of SEQ ID NO: 61. However, the written description in this case only sets forth one species of polypeptide consisting of the amino acid sequence of SEQ ID NO: 48 which is a fragment of SEQ ID NO: 32 having a molecular weight of about 90kDa and comprises the amino

acid sequence of SEQ ID NO: 61, and one species of polypeptide consisting of the amino acid sequence of SEQ ID NO: 49 which is a fragment of SEQ ID NO: 32 having a molecular weight of about 35 kDa and comprises the amino acid sequence of SEQ ID NO: 61.

The Written Description Guidelines for examination of patent applications indicates, "the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical characteristics and/or other chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show applicant was in possession of the claimed genus." (Federal register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 column 3) and (see MPEP 2164).

The specification teaches (page 9, lines 22-23) that CLCA molecules such as hCLCA2 (SEQ ID NO: 32) are normally cleaved into 90 and 35 kDa polypeptides. For example, the specification teaches (page 24, lines 2-11)that the human CLCA2 protein (SEQ ID NO: 32) cleaved into two subunits, one of which was identified as a 86 kDa protein and the second identified as a 34 kDa protein. With regards to the two subunits of hCLCA2 (SEQ ID NO: 32), the specification teaches (page 39, lines 14-22) that the 90 kDa, e.g., 86 kDa, subunit of hCLCA2 is represented by SEQ ID NO: 48 which contains a conserved motif of AFSRISSGTG (SEQ ID NO: 50) and the 35 kDa subunit of hCLCA2 is represented by SEQ ID NO: 49 which contains a conserved motif of GFSRVSSGGS (SEQ ID NO: 51). Thus, while the specification reasonably conveys one species of polypeptide consisting of the amino acid sequence of SEQ ID NO: 48 which is a fragment of SEQ ID NO: 32 having a molecular weight of about 90kDa and comprises the amino acid sequence of SEQ ID NO: 61, and one species of polypeptide consisting of the amino acid sequence of SEQ ID NO: 49 which is a fragment of SEQ ID NO: 32 having a molecular weight of about 35 kDa and comprises the amino acid sequence of SEQ ID NO: 61, the specification does not appear to reasonably describe possession of any and/or all polypeptides which are a fragment of SEQ ID NO: 32 having a molecular weight of about 90kDa or 35 kDa and comprising the amino acid sequence of SEQ ID NO: 61 as presently claimed. A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or by describing structural features common the genus that "constitute a substantial portion of the genus."

See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997): "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cNDA, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." The Federal Circuit has recently clarified that a DNA molecule can be adequately described without disclosing its complete structure. See Enzo Biochem, Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted the standard that the written description requirement can be met by "show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ....i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. " Id. At 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original).

The court has since clarified that this standard applies to compounds other than cDNAs. See University of Rochester v. G.D. Searle & Co., Inc., __F.3d__,2004 WL 260813, at *9 (Fed.Cir.Feb. 13, 2004). The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features that are common to the genus. That is, the specification provides neither a representative number of polypeptides that encompass the genus of polypeptides which are a fragment of SEQ ID NO: 32 having a molecular weight of about 90 kDa of 35 kDA and comprises the amino acid sequence of SEQ ID NO: 61 nor does it provide a description of structural features that are common to the polypeptides. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the disclosure is insufficient to describe the genus. Thus, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure(s) of the

encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, one species of polypeptide consisting of the amino acid sequence of SEQ ID NO: 48 which is a fragment of SEQ ID NO: 32 having a molecular weight of about 90kDa and comprises the amino acid sequence of SEQ ID NO: 61, and one species of polypeptide consisting of the amino acid sequence of SEQ ID NO: 49 which is a fragment of SEQ ID NO: 32 having a molecular weight of about 35 kDa and comprises the amino acid sequence of SEQ ID NO: 61, but not the full breadth of the claims, meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 7 is rejected under 35 U.S.C. 102(b) as being anticipated by Shimkets et al. (WO 01/40521 A2, 2001).

Shimkets et al. teach a peptide of about 10 amino acids comprising the amino acid sequence of SEQ ID NO: 61 (page 2092 to 2093, SEQ ID NO: 6864 of the WO document). Thus, because the claims do not appear to provide any indication as to what range is covered by the term about,

the peptide taught by Shimkets consisting of 14 an amino acid residues in length meets the limitation of about.

Claim 3 is rejected under 35 U.S.C. 102 (b) as being anticipated by Ruggeri et al. (US 5,340,727, 1994).

Ruggeri et al. teach (Figure 1A) an isolated and purified peptide which appears to be 100% identical to the instantly claimed polypeptide which is a fragment of SEQ ID NO: 32, wherein the polypeptide has a molecular weight of about 35 kDa and comprises the amino acid sequence of SEQ ID NO: 61. Thus, because the claims do not appear to provide any indication as to what range is covered by the term about, the peptide taught by Ruggeri et al. consisting of 293 amino acid residues having a molecular weight of about 33 kDa (see attached molecular weight calculator) meets the limitation of about 35 kDa. Moreover, "is" recited in claim 3 has been interpreted as inclusive or open-ended and does not exclude additional, unrecited elements or method steps. As such, the only fragment of SEQ ID NO: 32 that appears to be necessary is SEQ ID NO: 61.

Claim 1 is rejected under 35 U.S.C. 102 (b) as being anticipated by Guan et al. (J. Biol. Chem. 1992; 267: 10024-10030).

Guan et al. teach (page 10027, Fig. 2) an isolated and purified polypeptide which appears to be 100% identical to the instantly claimed polypeptide which is a fragment of SEQ ID NO: 32, wherein the polypeptide has a molecular weight of about 90 kDa and comprises the amino acid sequence of SEQ ID NO: 61. Thus, because the claims do not appear to provide any indication as to what range is covered by the term about, the peptide taught by Guan et al. consisting of 750 amino acid residues having a molecular weight of about 86 kDa (see attached molecular weight calculator) meets the limitation of about 90 kDa. Moreover, "is" recited in claim 3 has been interpreted as inclusive or open-ended and does not exclude additional, unrecited elements or method steps. As such, the only fragment of SEQ ID NO: 32 that appears to be necessary is SEQ ID NO: 61.

Conclusion

Claim 2, 4 and 8 appear to be free of the prior art, but are objected to as being dependent from a rejected independent claim. In the instant case, Wang et al. (US 6,426,072), considered the closest prior art to claim 2, teach a polypeptide which has 99.5% identity to the instantly claimed amino acid sequence of SEQ IDNO: 48. Adolf et al. (DE19924199, 2000), considered the closest prior art to claim 4, teach a polypeptide having an amino acid sequence which comprises the instantly claimed amino acid sequence of SEQ ID NO: 49 (page 18, SEQ ID NO: 2 of Adolf et al.). However, the polypeptide disclosed by Adolf et al. consists of 742 amino acid residues; and therefore, does not meet the claimed limitation of having a molecular weight of about 35 kDa. Reed et al. (WO 99/47674, 1999), considered to be the closest prior art to the peptide consisting of SEQ ID NO: 50, teach a polypeptide which comprises the instantly claimed amino acid sequence of SEQ ID NO: 50. Wang et al. (WO 00/61612, 2000), considered the closest prior art to the peptide consisting of SEQ ID NO: 51 or SEQ ID NO: 52, teach a polypeptide which comprises the instantly claimed amino acid sequence of SEQ ID NO: 51. Thus, neither Reed et al. or Wang et al. teach a peptide consisting of SEQ ID NO: 50, 51 or 52.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER

5/23/2006